

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

ASTELLAS INSTITUTE FOR
REGENERATIVE MEDICINE, and STEM
CELL & REGENERATIVE MEDICINE
INTERNATIONAL, INC.,

Plaintiffs,

v.

IMSTEM BIOTECHNOLOGY, INC.,
XIAOFANG WANG, and REN-HE XU,

Defendants.

C.A. No. 1:17-cv-12239

FILED UNDER SEAL

**LEAVE TO FILE GRANTED ON
01/09/2020 (Dkt. 141)**

**DEFENDANTS’ OPPOSITION TO PLAINTIFFS’ STATEMENT OF UNDISPUTED
MATERIAL FACTS IN SUPPORT OF THEIR MOTION FOR PARTIAL SUMMARY
JUDGMENT & COUNTERSTATEMENT OF ADDITIONAL MATERIAL OF FACTS**

Pursuant to Fed. R. Civ. P. 56 and Local Rule 56.1, Defendants ImStem Biotechnology Corp., Xiofang Wang, and Ren-He Xu (collectively, “Defendants”) hereby respond to the numbered paragraphs of Plaintiffs’ Statement of Undisputed Material Facts in Support of Their Motion for Partial Summary Judgment (“Plaintiffs’ SMF”) (Dkt. No. 110) and counterstatement of additional material facts as follows:

I. RESPONSES TO PLAINTIFFS’ SMF

As discussed in greater detail in Defendants’ Opposition to Plaintiffs’ Motion for Partial Summary Judgment, filed herewith, Plaintiffs’ motion for partial summary judgment turns on differing interpretations of a small number of undisputed facts, as well as a small number of disputed facts. Many of Plaintiffs’ SMF are not material the Court’s decision on Plaintiffs’ partial motion. Defendants are therefore leaving unaddressed certain technical and rhetorical

imprecision in Plaintiffs' SMF. Defendants reserve the right to address those errors when if and when they become material to the case.

A. Procedural History¹

1. Paragraph 1 is undisputed for the purposes of the present motion.

2. Paragraph 2 is undisputed for the purposes of the present motion, although Defendants clarify that Paragraph 2 summarizes Plaintiffs' allegations; Defendants dispute the truth of those allegations.

3. Paragraph 3 is undisputed for the purposes of the present motion, but clarify that Plaintiffs' characterization of Defendants' unjust enrichment claim is incomplete. Defendants refer the Court to Dr. Wang and ImStem's Answer and Counterclaims for a complete understanding of their unjust enrichment claim. (Dkt. No. 20, ¶¶ 39-52 & Prayer For Relief).

4. Paragraph 4 is undisputed for the purposes of the present motion.

5. Paragraph 5 is undisputed for the purposes of the present motion.

6. Paragraph 6 is undisputed for the purposes of the present motion.

7. Paragraph 7 is undisputed for the purposes of the present motion.

8. Paragraph 8 is undisputed for the purposes of the present motion, but Defendants clarify that Defendants' unjust enrichment claim (Count III) is substantively identical to such claim in Count II of Dr. Wang and ImStem's original Counterclaims.

9. To the extent that statements in Paragraph 9 are characterizations, opinions, or conclusions of fact, they are inappropriate and are denied. To the extent that such statements accurately quote the exact words of the document, they are undisputed. Defendants respectfully

¹ For convenience and to aid the Court's review, Defendants have reproduced the section headings used in Plaintiffs' SMF. In so doing, however, Defendants are not agreeing to such characterizations or summaries, and reserve all rights.

refer the Court to the contents of Defendants' Amended Answer and Counterclaims for the context of the quoted language.

10. Paragraph 10 is disputed. Defendants identify the issuance of the '956 and the '321 patents, without any shared ownership interest with the Defendants, as the value of the alleged benefit conferred, and further alleged that they were entitled to a constructive trust over the '956 and '321 patents as a result of Plaintiffs' unjust enrichment. (Dkt. No. 91, ¶¶ 58-63 & Prayer for Relief).

11. Paragraph 11 is disputed. Defendants did not specifically request monetary damages, but did, in fact, requested equitable relief, and also requested any relief that the Court deems just and proper, which may properly include monetary damages. (Dkt. No., 91 ¶¶ 49-63 & Prayer for Relief).

12. To the extent that statements in Paragraph 12 are characterizations, opinions, or conclusions of fact, they are inappropriate and are denied. To the extent that such statements accurately quote the exact words of the document, they are undisputed. Defendants respectfully refer the Court to the contents of Defendants' Amended Answer and Counterclaims, in particular paragraphs 49-93 & the Prayer For Relief, for the context of the quoted language.

13. Paragraph 13 is undisputed for the purposes of the present motion.

14. Paragraph 14 is undisputed for the purposes of the present motion.

15. Paragraph 15 is undisputed for purposes of the present motion, but Defendants clarify that the quoted language is just a portion of the Court's opinion and respectfully refer the Court to the entirety of the opinion for the context of the quoted language. (Dkt. No. 111).

16. Paragraph 16 is undisputed for the purposes of the present motion.

17. Paragraph 17 is undisputed for the purposes of the present motion.

18. Paragraph 18 is undisputed for the purposes of the present motion, but Defendants dispute that such subsection of Dr. Fortier's report is proper expert testimony and that she was qualified to render such opinions. Defendants further dispute Dr. Fortier's characterizations, conclusions, and opinions in this cited subsection of her expert report. *See* Declaration of Timothy R. Shannon in Support of Defendants' Opposition to Plaintiffs' Motion for Partial Summary Judgment ("Shannon SJ Oppn. Decl."), Ex. 15.

19. Paragraph 19O is undisputed for the purposes of the present motion.

20. Paragraph 20 is undisputed for the purposes of the present motion, but Defendants respectfully refer the Court to the entirety of Defendants' Second Amended Answer & Counterclaim for a complete understanding of what Defendants alleged.

21. Paragraph 21 is undisputed for the purposes of the present motion to the extent that it accurately quotes from the language under Defendants' Affirmative Defenses Nos. 5-9, but Defendants respectfully refer the Court to the entirety of Defendants' Second Amended Answer & Counterclaim for a complete understanding of what Defendants alleged.

22. To the extent that statements in Paragraph 22 are characterizations, opinions, or conclusions of fact, they are inappropriate and are denied. Paragraph 22 is undisputed for the purposes of the present motion, insofar as it merely restates the language quoted in Paragraph 21, above. The affirmative defenses themselves contain allegations. *See* Paragraphs 68-95, *infra*.

B. Drs. Lanza and Kimbrel are Inventors on U.S. Patent No. 9,745,551

23. Paragraph 23 of Plaintiffs' SMF is undisputed for the purposes of the present motion.

24. Paragraph 24 of Plaintiffs' SMF is undisputed for the purposes of the present motion.

25. Defendants dispute the adverb, “typically,” on the ground that it is vague as to quantity, era/time, and prior art. MSC-like cells have been derived from various sources.

26. Paragraph 26 of Plaintiffs’ SMF is undisputed for the purposes of the present motion, but Defendants note that they have disputed whether the “MSCs” derived by the original Kimbrel/Lanza method are true MSC’s as there is still uncertainty in the scientific community regarding the exact definition and properties of MSCs. *See generally* Shannon SJ Oppn. Decl., Ex. 14.

27. Paragraph 27 of Plaintiffs’ SMF is undisputed for the purposes of the present motion.

28. Paragraph 28 of Plaintiffs’ SMF is undisputed for the purposes of the present motion.

29. Paragraph 29 of Plaintiffs’ SMF is undisputed for the purposes of the present motion.

30. Defendants dispute Paragraph 30 to the extent it suggests that the sole purpose of the collaboration was to “run in an animal model” certain. *See, e.g.*, Oppn. to Mot. to Dismiss (Dkt. 28) at 1-3. Further, the cells had not yet been fully characterized. AIRM00013861.

31. Paragraph 31 of Plaintiffs’ SMF is undisputed for the purposes of the present motion.

32. Disputed. U.S. Provisional Patent Application No. 61/670,787 (“‘551 Provisional Application”) did not claim Astellas’s method of making HB-MSC’s. *See* ‘551 Provisional at Claims 1-27. Claim 1 references deriving “MSC-like” cells through the formation of hemangioblasts in a generic way, essentially as a precursor to subsequent claims, but did not claim the steps or details articulated in the original protocol from Kimbrel. The remaining

claims are primarily directed to the use of HB-MSC's – particularly for treating autoimmune diseases – which was the Defendants concept and contribution. *Id.* Further, the '551 Provisional, drafted by Dr. Wang without the benefit of counsel, also disclosed other inventive contributions (e.g. mitotic inactivation) solely from Drs. Wang and Xu. *Id.* at Abstract. Further, the protocol disclosed by Drs. Wang and Xu in the Provisional differed from the Astellas protocol in several significant ways, including but not limited to choice of culture medium, plating cell density, resuspending concentration, and duration of culture. *Compare id.* at 14 (“Derivation of hESC-HB-MSC”) with IMSTEM-0001528 (protocol from Dr. Lu, forwarded by Dr. Kimbrel).

33. Defendants dispute Paragraph 33 on the ground that it mischaracterizes the patent prosecution process. The '551 Patent issued from U.S. Application No.14/413,290 (filed Jan. 7, 2015 as a national phase of 'PCT/US2013/048291). *See* '551 Patent at cover.

34. Defendants dispute Paragraph 34 to the extent implicitly mischaracterizes the scope and nature of the claims of the '551 Patent. The claims are directed to a *particular* method of generating MSC-like cells from hESC's via a hemangioblast intermediary, that method including a particular GSK3-inhibitor preconditioning step. '551 Patent at Claim 1.

35. Paragraph 35 of Plaintiffs' SMF is undisputed for the purposes of the present motion.

36. Paragraph 36 of Plaintiffs' SMF is undisputed for the purposes of the present motion, although Defendants note the summary is ambiguous as to which “cells” at which stage are cultured; the Claim speaks for itself.

37. Defendants dispute Paragraph 37. Defendants have identified other scientific contributions and improvements over the prior art, including but not limited to contribution of a

GSK-3 inhibitor at a narrow concentration, *see* Rebuttal Expert Report of John M. Perry, PH.D (Nov. 1, 2019) ¶¶ 54-55, 58; the use of a specific GSK-3 inhibitor known as BIO, *id.* ¶ 58; the knowledge of cell characterization necessary to differentiate native MSCs from HB-MSCs and the idea to do so here, *see* Expert Rebuttal Report of Bruce Bunnell, PH.D. (Nov. 1, 2019) ¶¶ 30-31; therapeutic utility, *see id.*, the optimization of MSCs to treat multiple sclerosis, *id.* ¶¶ 35-36; the idea to screen HB-MSCs for low expression of IL-6, *id.* ¶¶ 50-51; and mitotically inactivating HB-MSCs in Claims 6 & 7 of the ‘551 patent, *id.* ¶¶ 55 -56. *See also generally* Sharkey SJ Decl. at Ex. 10 (Def.’s Amended Responses and Objections to Astellas First Set of Interrogatories (Nos. 1-21) (dated Oct. 14, 2019)) at 9-13. Further, Kimbrel and Lanza improperly included many of those improvements in their ‘321 Patent applications, the subject of Defendants’ counterclaims in this case. *See, e.g.*, Amended Answer and Counterclaims (Dkt. 91).

38. Paragraph 38 of Plaintiffs’ SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the document for a complete understanding of the text.

39. Paragraph 39 of Plaintiffs’ SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the document for a complete understanding of the text.

40. Paragraph 40 of Plaintiffs’ SMF is undisputed for the purposes of the present motion to the extent it accurately quotes the cited language, but Defendants object to the extent it does not include the Defendants’ objections. Defendants respectfully refer the Court to the entirety of the document for a complete understanding of the text. Further, Defendants subsequently amended their response based, in part, on a better-developed understanding of the

requirements of co-inventorship. *See generally* Sharkey SJ Decl. at Ex. 10 (Def.'s Amended Responses and Objections to Astellas First Set of Interrogatories (Nos. 1-21) (dated Oct. 14, 2019)).

41. Defendants dispute Paragraph 41 to the extent it suggests Defendants had an obligation to prove a negative or had the burden to produce evidence concerning the absence of any meaningful contribution by Dr. Lanza. It is Plaintiffs' burden to show that Dr. Lanza should, in fact, be a named inventor.

42. Paragraph 42 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the document for a complete understanding of the text.

43. Paragraph 43 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent it accurately quotes the cited language, but Defendants object to the extent it does not include the Defendants' objections. Defendants respectfully refer the Court to the entirety of the document for a complete understanding of the text. Further, Defendants subsequently amended their response. *See generally* Sharkey SJ Decl. at Ex. 10 (Def.'s Amended Responses and Objections to Astellas First Set of Interrogatories (Nos. 1-21) (dated Oct. 14, 2019)).

44. Paragraph 44 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent it accurately quotes the cited language, but Defendants object to the extent it does not include the Defendants' objections. Defendants respectfully refer the Court to the entirety of the documents for a complete understanding of the text. Further, Defendants renew their objection to the underlying Interrogatory to the extent it seeks or is interpreted to reveal attorney-client communications.

45. Paragraph 45 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent it notes that Defendants' amended answers differed from earlier responses – which is the entire purpose of amendment – but do object to the phrase “these statements” as ambiguous, and to the extent the paragraph implies Defendants had an obligation to prove a negative, produce evidence concerning the absence of any meaningful contribution by Drs. Kimbrel and Lanza over the prior art (including their own published ‘321 PCT), or otherwise opine on legal arguments concerning inventorship. It is Plaintiffs' burden to show that Drs. Kimbrel and Lanza should, in fact, be named inventors.

46. Defendants object to Paragraph 46 of Plaintiff's SMF as insolubly ambiguous. Among other things, the statement does not explain what is meant by “new” bases or whether that term is used in a temporal or differentiating sense. To the extent any response is required, the Defendants' interrogatory responses speak for themselves, and respectfully refer the Court to the entirety of the documents for a complete understanding of the text.

47. Defendants object to Paragraph 47 of Plaintiff's SMF as insolubly ambiguous. Among other things, the statement does not explain what is meant by “these amendments.” To the extent any response is required, the Defendants' interrogatory responses speak for themselves, and respectfully refer the Court to the entirety of the documents for a complete understanding of the text. Defendants do not dispute, for purposes of this motion, that Claim 1 of the ‘551 patent includes prior art, including some protocol steps shared by Drs. Kimbrel and Lanza.

48. Paragraph 48 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent it accurately quotes the cited language, but Defendants object to the extent it

does not include the Defendants' objections. Defendants respectfully refer the Court to the entirety of the documents for a complete understanding of the text.

49. Paragraph 49 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent it accurately quotes the cited language, but Defendants object to the extent it does not include the Defendants' objections. Defendants respectfully refer the Court to the entirety of the documents for a complete understanding of the text.

50. Disputed. Amended responses, by their nature, replace prior answers and thus "withdraw" the prior answers. Among other things, Kimbrel did not contribute or first carry out the low IL-6 screening recited in step (e). *See generally* Sharkey SJ Decl. at Ex. 10 (Def.'s Amended Responses and Objections to Astellas First Set of Interrogatories (Nos. 1-21) (dated Oct. 14, 2019)) at 9-10. Defendants further dispute Paragraph 50 on the ground that it is a legal conclusion rather than a factual statement.

51. Disputed. Dr. Wang testified that it was "up to the legal system to decide" whether Drs. Lanza and Kimbrel should be named as inventors. *See* SMF ¶ 52.

52. Paragraph 52 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the document for a complete understanding of the text.

53. Paragraph 53 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language. Defendants note that the statement relayed an offer made pursuant to FRE 408.

54. Paragraph 54 of Plaintiffs' SMF is undisputed for the purposes of the present motion.

55. Paragraph 55 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent that it roughly summarizes the Fortier and Brivanlou reports, but Defendants do not adopt those opinions, do not believe they accurately reflect the case, and repeat and incorporate by reference all objections to all Defendant statements and discovery responses referenced in those reports. Defendants further objects to the summary of those reports to the extent the summary purports, itself, to be a conclusion of law rather than a factual assertion.

56. Paragraph 56 of Plaintiffs' SMF is undisputed for the purposes of the present motion but note that Drs. Brivanlou and Perry were not asked to opine on whether Drs. Kimbrel and Lanza should be named inventors on any of the patents-in-suit. *See* SMF ¶¶ 59, 61.

57. Paragraph 57 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the document for a complete understanding of the text.

58. Paragraph 58 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the document for a complete understanding of the text.

59. Paragraph 59 of Plaintiffs' SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the transcript for a complete understanding of the text.

60. Defendants dispute Paragraph 60 of Plaintiffs' SMF. The label "alleged" is ambiguous and improper given Mr. Zerhuen's qualifications as the head of a major IP practice at a substantial firm, with literally decades of experience. Paragraph 60 apparently accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the transcript for a complete understanding of the text. Defendants note and reaffirm their objections

to the quoted question. Defendants further note that Dr. Zerhusen was asked about “something inventive,” an ambiguous term, and not about inventorship as a matter of law.

61. Paragraph 60 of Plaintiffs’ SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the transcript for a complete understanding of the text. Defendants note and reaffirm their objections to the quoted question. Defendants note that Dr. Perry was asked about whether Kimbrel and Lanza “should be” co-inventors without any apparent discussion about inventorship as a matter of law.

62. Defendants dispute Paragraph 62. The phrase “the method” is ambiguous. The phrase “significant contribution” also connotes contributions and inventorship apart from the prior art. At the time the ‘551 PCT was filed, the ‘321 PCT had already been rendered public and Kimbrel and Lanza’s “contributions” to the art; the basic protocol had been rendered prior art for purposes of subsequent applications such as the ‘551 PCT. Even though Drs. Kimbrel and Lanza (and Dr. Lu) had developed something that the PTO deemed patentable (without knowledge of Lu), and Kimbrel and Lanza had shared their basic protocol with Drs. Wang and Xu, the protocol was no longer a contribution as of the ‘551 PCT filing date as a matter of law.

63. Paragraph 63 of Plaintiffs’ SMF is undisputed for the purposes of the present motion to the extent that it accurately quotes the cited language but Defendants respectfully refer the Court to the entirety of the document for a complete understanding of the text. Defendants dispute that the specification of the ‘551 patent describes the “present invention”; the claims of a patent describe the invention.

64. Defendants do not dispute that Plaintiffs possessed certain technology related to generating a specific type of mesenchymal-stem-like-cells (although not yet confirmed or

characterized at the time of their first meeting) and that they shared such information with Defendants for purposes of the joint collaboration, but deny that it was an inventive contribution to the ‘551 patent. Rather, it was prior art at the time of the ‘551 PCT filing.

65. Defendants do not dispute that Plaintiffs possessed certain technology related to generating a specific type of mesenchymal-stem-like-cells (although not yet confirmed or characterized at the time of their first meeting) and that they shared such information with Defendants during the joint collaboration, but dispute that it was an inventive contribution to the ‘551 patent. Rather, it was prior art at the time of the ‘551 PCT filing.

66. Paragraph 66 of Plaintiffs’ SMF is undisputed for the purposes of the present motion but note that Drs. Brivanlou and Perry were not asked to opine on whether Drs. Kimbrel and Lanza should be named inventors on any of the patents-in-suit. *See* SMF ¶¶ 59, 61.

67. Defendants do not dispute that Plaintiffs possessed certain technology related to generating a specific type of mesenchymal-stem-like-cells (although not yet confirmed or characterized at the time of their first meeting) and that they shared such information with Defendants during the joint collaboration, but dispute that it was an inventive contribution to the ‘551 patent. Rather, it was prior art at the time of the ‘551 PCT filing.

C. Defendants’ Lack of Proof for Affirmative Defenses to Breach of Contract

68. Paragraph 68 is disputed. Plaintiffs did not “substantively respond” to Defendants interrogatories relating to Plaintiffs’ breach of contract claims. Rather, instead Plaintiffs merely pasted sections of the Expert Report of Dr. Lisa Fortier – who is not an attorney and is not qualified to make legal determinations on what comprises a contract or what makes a breach of contract – into the body of their responses. *See* Declaration of Lauren K. Sharkey In Support of

Astellas' Motion for Summary Judgment, Exh. 18 [Dkt. No. 129] (Astellas Resp. to Defs. Fifth Set of Interrogatories (Oct. 11, 2019)). Plaintiffs have not supplemented their response.

69. Paragraph 69 is undisputed to the extent that it accurately quotes from Plaintiffs' Interrogatory No. 36, but Defendants dispute that such interrogatory is entirely proper and respectfully refer the Court to Defendants' general and specific objections. (Ex. 19 to Sharkey Declaration, Oct. 11, 2019 Defs. Resp. and Objs).

70. Paragraph 70 is undisputed to the extent that it accurately quotes portions of Defendants' specific objection to Astellas' Interrogatory No. 6, but dispute that it fully captures all of Defendants' specific objections or that it also includes the general objections (which are incorporated therein by reference). For example, one such general objection is the extent to which an interrogatory is inconsistent with the applicable District Court Local Rules. Local Rule 26.5 includes a "uniform definition" of "state the basis" with respect to interrogatories. Defendants respectfully refer the Court to the entirety of their objections to Plaintiffs' Interrogatory No. 6, which incorporate by reference Defendants' general objections. (Ex. 19 to Sharkey Declaration, Oct. 11, 2019 Defs. Resp. and Objs).

71. Paragraph 71 is undisputed for purposes of the present motion to the extent that it accurately quotes a portion of Defendants' written response to Plaintiffs' Interrogatory No. 36, but Defendants clarify that their written response is subject to their general and specific objections to Interrogatory No. 36. Defendants dispute the quoted language is the "entirety of the Defendants' substantive response to Interrogatory No. 36," as such response also includes (pursuant to Fed. R. Civ. P. 33(d)) the content of the specifically identified documents.

72. Paragraph 72 is not material for the present motion. Regardless, Paragraph 72 is undisputed for purposes the present motion.

73. Paragraph 74 is not material for the present motion. Regardless, Paragraph 73 is undisputed for purposes the present motion.

74. Paragraph 74 is not material for the present motion. Regardless, Paragraph 74 is undisputed for purposes the present motion.

75. Paragraph 75 is not material for the present motion. Regardless, Defendants dispute the implication that their response to Plaintiffs' Interrogatory No. 36, which was subject to Defendants' general and specific objections, was deficient. Otherwise, Paragraph 75 is undisputed for purposes the present motion.

76. Paragraph 76 is undisputed for purposes of the present motion, but clarify that the Court did not "invite" Defendants to take additional depositions, but rather gave them leave to do so – if they chose. (Dkt. 111 at 7). Defendants further clarify that the Court also gave Plaintiffs leave to take additional depositions. (*Id.*)

77. Paragraph 77 is not material for the present motion. Regardless, Paragraph 72 is undisputed for purposes the present motion. Defendants state that "opining" on their affirmative defenses would be rendering a legal opinion, which Dr. Fortier impermissibly did in her expert report. As Dr. Fortier admitted at her deposition, she is not qualified to give a legal opinion on whether Plaintiffs have a valid contract claim and, if so, whether Defendants breached any such alleged contract.

78. Paragraph 78 is not material for the present motion. Regardless, Paragraph 72 is undisputed for purposes the present motion. Defendants state Dr. Fortier "opining" on Plaintiffs' breach of contract claim is nothing more than an impermissible legal opinion –which she admitted that she is not qualified to give.

79. Paragraph 79 is disputed. Defendants identified Exhibits 1-3 to the Declaration of Lauren Sharkey (Dkt. No. 99) and/or the Declaration of Benjamin M. Stern in support of Defendants' Opposition to Plaintiffs' Motion for Leave to Amend (Dkt. No. 110 (sealed version)). Pursuant to Fed. R. Civ. P. 33(d), those documents were properly incorporated by reference in Defendants' response to Plaintiffs' Interrogatory No. 36. (Defs. Resp. to Interrogatory No. 36 (Oct. 11, 2019)). Moreover, Defendants dispute the suggestion that it is their burden to demonstrate the *absence* of the existence of a contract between the parties in the first instance. Rather, it is Plaintiffs' burden to prove a valid and binding contract between the parties.

80. Paragraph 80 is not material for purposes of the present motion. Regardless, Paragraph 80 is undisputed for purposes of the present motion to the extent that the language is a partial quote from paragraph 3 of Defendants' Second Amended Answer, but Defendants dispute that it is a complete summary of Defendants' statement in that paragraph and respectfully refer the Court to the entirety of that paragraph for a complete understanding of the context. (Dkt. No. 114, ¶ 3).

81. Paragraph 81 is not material for purposes of the present motion. Regardless, Paragraph 81 is undisputed for purposes of purposes of the present motion.

82. Paragraph 82 is not material for purposes of the present motion. To the extent that statements in Paragraph 82 are characterizations, opinions, or conclusions of fact, they are inappropriate and are denied. To the extent that such statements accurately quote the exact words of the document, they are undisputed. Defendants respectfully refer the Court to the contents of the cited documents for the context of the quoted language.

83. Paragraph 83 is undisputed to the extent it is Plaintiffs' own characterization of their breach of contract claim, but Defendants respectfully refer the Court to Plaintiffs' First Amended Complaint for the factual allegations of Plaintiffs' claim.

84. Paragraph 84 is undisputed to the extent that it accurately quotes from portions of a lengthy email thread, but Defendants respectfully refer the Court to the entirety of the email communications for a complete understanding of the parties' statements.

85. Paragraph 85 is undisputed to the extent that it accurately quotes from portions of a lengthy email thread, but Defendants respectfully refer the Court to the entirety of the email communications for a complete understanding of the parties' statements.

86. Paragraph 86 is undisputed to the extent that it accurately quotes from portions of a lengthy email thread, but Defendants respectfully refer the Court to the entirety of the email communications for a complete understanding of the parties' statements.

87. Paragraph 87 is undisputed for purposes of the present motion.

88. Paragraph 88 is undisputed to the extent that it accurately quotes from portions of a lengthy email thread, but Defendants respectfully refer the Court to the entirety of the email communications for a complete understanding of the parties' statements.

89. Paragraph 89 is undisputed to the extent that it accurately quotes from portions of a lengthy email thread, but Defendants respectfully refer the Court to the entirety of the email communications for a complete understanding of the parties' statements.

90. Paragraph 90 is undisputed to the extent that it accurately quotes from portions of a lengthy email thread, but Defendants respectfully refer the Court to the entirety of the email communications for a complete understanding of the parties' statements.

91. Paragraph 91 is not material for purposes of the present motion. To the extent that statements in Paragraph 91 are characterizations, opinions, or conclusions of fact, they are inappropriate and are denied. To the extent that such statements accurately quote the exact words of the document, they are undisputed. Defendants respectfully refer the Court to the contents of the cited documents for the context of the quoted language.

92. Paragraph 92 is not material for purposes of the present motion. To the extent that such statements accurately quote the exact words of the deposition transcript, they are undisputed. Defendants respectfully refer the Court to the contents of the deposition transcript for the context of the quoted language.

93. Paragraph 93 is not material for purposes of the present motion. To the extent that such statements accurately quote the exact words of the deposition transcript, they are undisputed. Defendants respectfully refer the Court to the contents of the deposition transcript for the context of the quoted language.

94. Paragraph 94 is not material for purposes of the present motion. To the extent that statements in Paragraph 94 are characterizations, opinions, or conclusions of fact, they are inappropriate and are denied. Defendants respectfully refer the Court to the contents of the cited documents for the full context.

95. Paragraph 95 is undisputed for purposes of the present motion to the extent that Dr. Bell, in his expert report, offered an opinion on financial harm relating to each of Plaintiffs' state law claims, but disputed that Dr. Fortier properly offered any expert opinion over financial harms allegedly suffered by Plaintiffs. Further disputed that Plaintiffs offered any opinion by Dr. Bell or Dr. Fortier concerning specific financial harm resulting from "the loss of time and

expenses spent on the deceptive collaboration.” Defendants respectfully refer the Court to the contents of the cited documents for the full context.

D. Defendants Lack of Proof for Alleged Unjust Enrichment

96. Paragraph 96 is not material for purposes of the present motion. Regardless, Paragraph 96 is undisputed for purposes of the present motion to the extent that it accurately quotes from a portion of a deposition transcript, but clarifying that Defendants are not asserting specific financial damages. Disputed that the quoted testimony constitutes an “admission.”

97. Paragraph 97 is not material for purposes of the present motion. Regardless, Paragraph 97 is undisputed for purposes of the present motion to the extent that it accurately quotes, in part, Plaintiffs’ Interrogatory No. 35, but Defendants respectfully refer the Court to the contents of the cited documents for the full context.

98. Paragraph 98 is not material for purposes of the present motion. Regardless, Paragraph 98 is undisputed for purposes of the present motion to the extent that it accurately quotes from a portion of Defendants’ response to Interrogatory No. 35, but clarifies that this portion does not include the entirety of Defendants’ response (including general and specific objections). Defendants respectfully refer the Court to the contents of the cited documents for the full context. Defendants dispute the implication that this quoted language is somehow a statement as to non-monetary damages.

99. Paragraph 99 is not material for purposes of the present motion. Regardless, Paragraph 99 is undisputed for purposes of the present motion.

100. Paragraph 100 is not material for purposes of the present motion. Regardless, Paragraph 100 is undisputed for purposes of the present motion.

101. Paragraph 101 is not material for purposes of the present motion. Regardless, Paragraph 101 is undisputed for purposes of the present motion.

102. Paragraph 100 is not material for purposes of the present motion. Regardless, Paragraph 102 is disputed to the extent it implies that Mr. Green's statements regarding unjust enrichment apply to Defendants' claims in this case; Mr. Green's opinion was in specific rebuttal to Dr. Bell's opinion on Plaintiffs' unjust enrichment, and the quoted language is merely a generalized statement about unjust enrichment claims. Defendants respectfully refer the Court to the contents of the cited document for the full context.

103. Paragraph 103 is not material for purposes of the present motion. Regardless, Paragraph 103 is disputed to the extent it implies that Mr. Green's testimony statements regarding unjust enrichment apply to Defendants' claims in this case; Mr. Green's statement was in specific rebuttal to Dr. Bell's opinion on Plaintiffs' unjust. Defendants respectfully refer the Court to the contents of the cited document for the full context.

104. Paragraph 104 is not material for purposes of the present motion. Regardless, Paragraph 104 is undisputed for purposes of the present motion, but Defendants clarify that Mr. Green's failure to offer an opinion on specific monetary damages resulting from Defendants' unjust enrichment claim does not exclude Defendants' pleaded non-monetary damages flowing from Plaintiffs' unjust enrichment.

105. Paragraph 105 is not material for purposes of the present motion. Regardless, Paragraph 105 is undisputed for purposes of the present motion, but Defendants clarify that Mr. Green's failure to offer an opinion on specific monetary damages resulting from Defendants' unjust enrichment claim does not exclude Defendants' pleaded non-monetary damages flowing from Plaintiffs' unjust enrichment.

106. Paragraph 106 is not material for purposes of the present motion. Regardless, Paragraph 105 is undisputed for purposes of the present motion

107. Paragraph 107 is not material for purposes of the present motion. Regardless, Paragraph 107 is undisputed for purposes of the present motion to the extent that Dr. Bunnell did not a specific opinion as to Defendants' unjust enrichment claim. Dr. Bunnell did, in fact, offer an opinion as to the underlying facts that comprise Defendants' unjust enrichment claim, namely Dr. Wang and Dr. Xu's contributions to the '321 and '956 patents.

108. Paragraph 108 is not material for purposes of the present motion. Regardless, Paragraph 108 is undisputed for purposes of the present motion to the extent that Dr. Bunnell did not offer a specific opinion as to Defendants' unjust enrichment claim. But, Dr. Bunnell did, in fact, offer an opinion as to the underlying facts that comprise Defendants' unjust enrichment claim, namely Dr. Wang and Dr. Xu's contributions to the '321 and '956 patents.

109. Paragraph 109 is not material for purposes of the present motion. Regardless, Paragraph 109 is undisputed for purposes of the present motion to the extent that it accurately quotes from a snippet of Dr. Bunnell's testimony. But, Dr. Bunnell did, in fact, offer an opinion as to the underlying facts that comprise Defendants' unjust enrichment claim, namely Dr. Wang and Dr. Xu's contributions to the '321 and '956 patents.

110. Paragraph 110 is not material for purposes of the present motion. Regardless, Paragraph 110 is undisputed for purposes of the present motion.

111. Paragraph 111 is not material for purposes of the present motion. Regardless, Paragraph 111 is undisputed for purposes of the present motion to the extent that Dr. Perry did not offer a specific opinion as to Defendants' unjust enrichment claim. But, Dr. Perry did, in

fact, offer an opinion as to the underlying facts regarding Dr. Wang and Dr. Xu's work with respect to the '551 patent.

112. Paragraph 112 is not material for purposes of the present motion. Regardless, Paragraph 112 is undisputed for purposes of the present motion.

113. Paragraph 113 is not material for purposes of the present motion. Regardless, Paragraph 113 is undisputed for purposes of the present motion to the extent that it accurately quotes from a snippet of Dr. Perry's testimony. But, Dr. Perry did, in fact, offer an opinion as to the underlying facts regarding Dr. Wang and Dr. Xu's work with respect to the '551 patent.

114. Paragraph 114 is not material for purposes of the present motion. Regardless, Paragraph 114 is undisputed for purposes of the present motion.

115. Paragraph 115 is not material for purposes of the present motion. Regardless, Paragraph 115 is undisputed for purposes of the present motion.

116. Paragraph 116 is not material for purposes of the present motion. Regardless, Paragraph 116 is undisputed for purposes of the present motion.

117. Paragraph 117 is disputed. Defendants have produced evidence demonstrating that they are entitled to equitable relief in the form of a constructive trust over the '331 and '956 patents, as Defendants provided key contributions to such patents. *See, e.g.*, Shannon SJ Oppn. Decl., Ex. 14 at. ¶¶ 65 – 89.

II. COUNTERSTATEMENT OF ADDITIONAL MATERIAL FACTS

118. In August 2011, Drs. Kimbrel and Lanza shared with Drs. Wang and Xu a basic protocol for differentiating hESCs into embryoid bodies into hemangioblasts and then "MSCs." *See* Astellas' Statement of Undisputed Material Facts in Support of Its Motion for Partial Summary Judgment (hereinafter "ASMF") (Dkt. No. 130) ¶ 29.

119. The ‘551 patent concerns a particular protocol for differentiating hESCs into MSCs. Some of the claimed steps entail the process of differentiating hESCs into embryoid bodies, then hemangioblasts, then MSCs. *See generally* ‘551 Patent (Sharkey SJ Decl. Ex. 2) at Claim 1, steps b-e.

120. On November 30, 2011, Plaintiffs filed a provisional application, No. 61/565,358 (“‘321 Provisional”), concerning their four-step process. *See* Shannon SJ Oppn. Decl. Ex. 1.

121. On November 30, 2012, Plaintiffs filed a non-provisional application, No. 13/691,349 (“‘321 Non-Provisional”) and a corresponding international application, PCT/US2012/067464 (“‘321 PCT”). *See id.*

122. On June 6, 2013, the ‘321 PCT published as WO2013/082543. Shannon SJ Oppn. Decl. Ex. 2.

123. Upon publication, the entire contents of the ‘321 PCT became public. *Id.*

124. Dr. Wang noticed the publication of the ‘321 PCT and forwarded it to his patent prosecutor on June 20, 2013. *See* Shannon SJ Oppn. Decl. Ex. 3 (Email from Wang to Susie S. Cheng, Esq. dated June 20, 2013 10:49 PM) (attaching WO2013/082543 (published version of ‘321 PCT)) (IMSTEM-0043610).

125. The publishing of the ‘321 PCT publicized the concept of “generating mesenchymal stromal cells [by] culturing hemangioblast cells under conditions that give rise to mesenchymal stem cells.” Shannon SJ Oppn. Decl. Ex. 2 (‘321 PCT ¶ 16).

126. It also it set forth detailed descriptions of the process:

[T]he hemangioblasts may be differentiated from pluripotent cells by a method comprising (a) culturing said pluripotent cells to form clusters of cells.

[T]he hemangioblasts are differentiated from pluripotent cells by a method further comprising: (b) culturing said single cells in the presence of at least one growth factor in an amount sufficient to induce the differentiation of said clusters

of cells into hemangioblasts.

[T]he method further comprises (c) dissociating said clusters of cells, optionally into single cells. In another aspect, the method further comprises (d) culturing said hemangioblasts . . . to expand the hemangioblasts or hemangio-colony forming cells.

[T]he method generates at least 80 . . . or 150 million mesenchymal stromal cells.

See Shannon SJ Oppn. Decl. Ex. 2 (‘321 PCT ¶¶ 19-22).

127. The ‘321 PCT included a set of corresponding claims, many of them covering the same process. *See, e.g.*, Shannon SJ Oppn. Decl. Ex. 2 (‘321 PCT at claims 46, 58, 61, 66, 72, 73).

128. On June 27, 2012 Defendants filed PCT/US13/48291 (“‘551 PCT”). *See* Shannon SJ Oppn. Decl. Ex. 4.

129. The ‘551 PCT disclosed the use of a certain concentration of GSK3 inhibitor to precondition the hESCs in a process to generate MSCs via a hemangioblast intermediary. *Id.*

130. On January 7, 2015, Defendants domesticated their ‘551 PCT by filing “national phase” application No. 14/413,290 (“‘551 Non-Provisional”) (filed on January 7, 2015),

131. Defendants disclosed the Plaintiffs ‘321 PCT to the patent office. *See* Shannon SJ Oppn. Decl. Ex. 6 (Defendants’ Information Disclosure Statement, filed on 1 June 2016).

132. The Examiner reviewed the ‘321 PCT and compared it to the ‘551 Non-Provisional. *See* Shannon SJ Oppn. Decl. Ex. 7.

133. On July 28, 2016, the Examiner issued a non-final Office Action rejecting the Defendants' claims as anticipated over the ‘321 PCT – indicating the disclosures in the two patents (‘321 PCT and ‘551 Non-Provisional) were identical to each other. Shannon SJ Oppn. Decl. Ex. 7.

134. The Defendants submitted an Amendment in which they amended claim 1 to affirmatively require the step of culturing hESCs in a serum free medium “with at least one GSK3 inhibitor at a concentration ranging from 0.05 μ M to 0.2 μ M, wherein the hESCs are cultured in the absence of feeder cells.” *See* Shannon SJ Oppn. Decl. Ex. 8. at 7-8.

135. In this amendment, the Defendants pointed out that the ‘321 PCT – *i.e.* the prior art as of 21 days before their ‘551 PCT was filed – did not describe or suggest the GSK3 inhibitor limitations in amended claim 1. *Id.*

136. The Examiner concluded that it would not have been obvious to use GSK3 inhibitor in the claimed concentration in the claimed context. *See* Shannon SJ Oppn. Decl. Ex. 9 (Expert Report of Bryan Zerhusen) ¶ 24.

137. In his Reasons for Allowance, the Examiner stated that the claims were allowable because “the claims now require the presence of a GSK3 inhibitor at a specific concentration that results in the production of hES-MSCs with the specific characteristics recited by the claims” and that “[t]his limitation overcomes the rejections of record [*i.e.*, in the July 28, 2016 non-final Office Action].” Shannon SJ Oppn. Decl. Ex. 10 at 4.

138. In 2019, Plaintiffs disclosed information that indicated that Astellas’ senior management knew about Plaintiffs’ state-law causes of action more than three years (four, based on the privilege log) prior to filing the Complaint. *See generally* Defs’ Mot. to Amend Complaint (Dkt. No. 106) at 3-4, 6; Defs’ Mot. for Partial SJ (Dkt. No. 135) at 2.

139. The Court allowed Defendants to add a statute of limitations defense. (Dkt. No. 85).

140. In response to this new defense, Plaintiffs brought a breach of contract claim against the Defendants. ASMF ¶ 13.

141. In a Motion for Leave, Plaintiffs identified three emails which made up what they contended was a contract. *See* Mot. for Leave (Dkt. No. 97) at 5.

142. Their proposed Amended Complaint referenced the same three emails. *See* First Amended Complaint (Dkt. No. 113) ¶¶ 5, 37, 39, 89.

143. The parties exchanged written discovery in the form of interrogatories. Sharkey SJ Decl. Exs. 18 – 19.

144. In response to Defendants’ interrogatories asking the Plaintiffs to identify what comprises the “Alleged Contract,” the Plaintiffs reiterated several long portions of the Expert Report of Dr. Lisa Fortier. *See* Sharkey SJ Decl. Ex. 18.

145. In response to Plaintiffs’ interrogatories regarding Defendants’ breach of contract defenses, Defendants identified Exhibits 1-3 to the Declaration of Lauren Sharkey (Dkt. No. 99) and/or the Declaration of Benjamin M. Stern in support of Defendants’ Opposition to Plaintiffs’ Motion for Leave to Amend. (Dkt. No. 110).

Dated: January 10, 2020

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CERTIFICATE OF SERVICE

I hereby certify that on January 10, 2020, I caused a true copy of the foregoing document to be served upon all counsel of record via the Court's CM/ECF electronic filing system.

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